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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,279	12/11/2001	Johnny Paul Speir	140-067a	2332
7590		03/29/2007		
Ward & Olivo				
708 Third Ave				
New York, NY 10017				
			EXAMINER	
			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/29/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/014,279

Applicant(s)

SPEIR, JOHNNY PAUL

Examiner

Jerry Lin

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

### ***Status of the Claims***

Claims 30-33 are under examination.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 30-33 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Dasseux et al. (US 2002/0019023 A1, cited previously).

The instant claims are drawn to a method of analyzing a drug-dosed sample using a Mass Spectrometer which includes ionizing a drug-dosed

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sample, introducing the ions into an analysis region, monitoring the ions, detecting changes, determining the molecular weight of each species, identifying species by comparing the empirical formula to a database and determining the chemical structure of a large molecule.

Regarding claim 30, Dasseux et al. disclose a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample with metabolic products (page 12, paragraph 0117- page 13, paragraph 0127; page 10, paragraphs 0090-0091); introducing said ions to the analysis region of a mass spectrometer (page 13, paragraph 0132-page 14, paragraph 0136); continuously monitoring the ions and detecting changes to the sample (page 15, paragraph 0153); determining the molecular weight of each species present in a sample to determine the empirical formula and identifying each species by comparing the empirical formula to a database of formulas (page 17, paragraph 0169). Furthermore, Dasseu et al. teach determining a chemical structure of a large molecule by utilizing said identified species (page 17, paragraphs 0171-0176).

Regarding claim 31, Dasseux et al. teach updating databases with the changes that are detected (page 18, paragraph 0183; page 19, paragraphs 0186-0187).

Regarding claim 32, Dasseux et al. teach where the mass spectrometer is a FTMS (page 3, paragraph 0022).

Regarding claim 33, Dasseux et al. teach using electrospray ionization (page 13, paragraph 0125) as well as chemical ionization (page 12, paragraph 0118). Both of these methods are forms of Atmospheric Pressure Ionization.

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Response to Arguments

4. The Applicants first respond to this rejection by stating that the present invention does not need a pre-digesting step of a known large molecule. However, this is unpersuasive because the instant claims contain no such limitation and the instant claims contains the transitional language of "comprising" such suggests that the invention may have additional steps other than those recited.

The Applicants then state that Dasseux et al. teach away from a step of identifying a fragment species because that database did not exist. First, an argument that states that a reference teaches away from the claimed invention is not relevant to a rejection made under 35 U.S.C. §102, although it may be relevant a rejection made under 35 U.S.C. §103. Secondly, as the Examiner stated before, Dasseux et al. are stating that the databases must be compiled before the peaks can be identified. Once the databases are compiled, Dasseux et al.'s method may be used to identify the peaks. Similarly in the last three steps of applicants' claim 30, if a database does not contain the empirical formula determined from the molecular weight, that species cannot be identified from that database. Dasseux et al. faces the same situation, and thus anticipates the instant claims.

This rejection is maintained from the previous office action.

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***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

JL

